

REMARKS

Entry of the foregoing and further and favorable consideration of the subject application is respectfully requested and such action is earnestly solicited.

As correctly stated in the Official Action, Claims 1, 3, 5, 16, and 25-28 are pending in the present application. Claims 1, 3, 5, 16, and 25-28 stand rejected.

By the present amendment, all pending claims have been amended to recite a composition comprising a green tea extract. Dependent claims have been amended so as to be consistent with the claims from which they depend. These amendments are supported, at least, by Claims 1-5, as originally filed. No new matter has been added.

Rejections Under 35 U.S.C. § 102(b)

Claims 1, 3, 25, and 26 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Yasuda et al. The Examiner argues that Yasuda et al. disclose a composition for decreasing halitosis containing an 80% alcoholic extract of green tea. The Examiner further suggests, albeit **erroneously**, that Applicants disclosed that an 80% alcohol extracted green tea extract **inherently** contains 20-30% catechols and 5-10% caffeine. Thus, the Examiner concludes that the presently claimed invention and the extract of Yasuda et al. must be the same because allegedly the same plant material was extracted. This rejection is respectfully traversed.

Initially, Applicants respectfully point out that "green tea" is merely a generic term for an extremely broad class of at least several hundred plant varieties, all deriving from the *Camellia sinensis* plant. Moreover, as Applicants have previously argued, all green

teas are not created equal, at least with respect to the catechol and caffeine content. The Declaration of Max Rombi, submitted previously, contains data pertaining to the catechol and caffeine content of different types of green tea and with different extraction solvents. As discussed in Paragraph 9 of the Declaration, several green teas were subjected to the exact same extraction with 80% ethanol, yet not every green tea produces the proportions and amounts of catechols and caffeine shown to be efficacious in the presently claimed invention. To meet the limitations of the claims, a green tea extract **must contain** from 20% to 50% by mass of catechols and from 5% to 10% of caffeine. As seen from Table 1 in the Declaration, it is not necessarily so that a particular green tea variety meets the necessary claim limitations when using an 80% ethanol extract. Therefore, contrary to the Examiner's statement, it has been, and continues to be, the Applicant's position that it is **not "inherent"** that an 80% ethanol (or any other extraction solvent, for that matter) extract possesses the particular proportion and amounts of catechols and caffeine required by the present claims.

Mr. Rombi's Declaration further demonstrates that varying the content of the extraction solvent itself influences the proportion and amounts of catechols and green tea. Paragraph 10 of the declaration shows the variation in content that arises, with the same green tea, with different extraction solvents. Thus, even varying the extraction solvent has an important impact on whether an extract that meets the present claim limitations is obtained.

It is well established that in order for prior art to anticipate a claimed invention the inherency must be certain. *Ex parte Cyba*, 155 USPQ 756 (POBA 1966). The fact that a

prior art article "may" inherently have the characteristics of the claimed product is not sufficient. *Ex parte Skinner*, 2 USPQ2d 1788 (BPAI 1986). Inherency must be a necessary result and not merely a possible result. *In re Oelrich*, 212 USPQ 323 (CCPA 1981). Applicants have established via the Declaration of Max Rombi that the levels of catechols and caffeine in tea extracts widely vary depending on the type of green tea and the extraction solvent used.

The Examiner has provided no evidence that the green tea of Yasuda, beyond the use of an 80% ethanol extraction, possesses the quantities and proportions required by the presently claimed invention. Applicants have demonstrated above that the 80% ethanol extraction is not a sufficient or accurate indicator of whether the green tea extract of Yasuda contains 20-50% by mass of catechols and 5-10% of caffeine. Yasuda has given no indication of such content. In fact, upon extracting the green tea with 80% ethanol, the extract is not analyzed at all, but rather is immediately chromatographed to obtain fractions containing particular tea catechins. Yasuda adds these separately fractionated catechins to chewing gum to determine the effect on halitosis, an effect so remote from the presently claimed invention so as to be completely unrelated. The proportion and amount of caffeine, an essential element of the synergistic combination, is not even mentioned in Yasuda. One skilled in the art would **not** consider Yasuda et al. to disclose a combination of catechols and caffeine. Yasuda et al. fail to disclose synergistic thermogenic and anti-lipase levels of catechols and caffeine, as in the presently claimed invention. At most, Yasuda et al. disclose that tea catechins, alone, can be used to depress bad breath.

Thus, in light of Applicant's data regarding the variability in the catechol and caffeine content even with a particular extraction solvent, the failure of Yasuda to indicate the particular type of green tea used, the lack of any analysis by Yasuda on the green tea extract itself, and the failure to disclose whether any caffeine is present, much less the amounts recited in the present claims, there is nothing in the Yasuda publication that is of use to the Examiner in concluding that the present claims are anticipated. Yasuda et al. do not disclose a composition containing a green tea extract with the recited amounts of catechols and caffeine. Moreover, Yasuda et al. do not disclose a composition suitable for oral administration as Yasuda et al. merely describe chewing gum with tea catechins to depress bad breath.

Applicants respectfully submit that the Examiner has not established a *prima facie* case of anticipation based on the Yasuda publication. Withdrawal of this rejection is respectfully requested. **In light of the fact that the recited levels of catechols and caffeine are not inherent, if the Examiner insists on maintaining this rejection, Applicants respectfully request that the Examiner explicitly point out where Yasuda et al. disclose or suggest a composition with a green tea extract with the claimed amounts of catechols and caffeine.**

Rejections Under 35 U.S.C. § 103(a)

Claims 5, 16, and 26-28 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Yasuda et al. (1991). The Examiner acknowledges that Yasuda et al. do not disclose the particular milligram amounts of EGCG and caffeine. However, the Examiner

argues that the ordinary artisan would have recognized that the claimed amounts of EGCG and caffeine were all within the ratio obtained in a 80% ethanol green tea extract. The Examiner also notes that the skilled artisan would have been motivated to have extracted green tea on a large scale. This rejection is respectfully traversed.

In order to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation to modify the reference or combine reference teachings, (2) there must be a reasonable expectation of success, and (3) the prior art reference(s) must teach or suggest all of the claim limitations. *See* M.P.E.P. §2142. Applicants respectfully submit that the Examiner has not established a *prima facie* case of obviousness.

Applicants respectfully submit that the remarks made above under the 35 U.S.C. § 102(b) rejection are equally applicable to the rejection under 35 U.S.C. § 103(a). Claims 5, 16, 27, and 28 recite a green tea extract with particular amounts of catechols and caffeine. Specifically, Claims 5 and 27 recite from 250 mg to 500 mg of catechols, and from 50 to 200 mg of caffeine. Claims 16 and 28 recite about 375 mg of catechols and 150 mg of caffeine. These amounts were found to be efficacious in the present specification.

The Examiner seems to argue that because Yasuda et al. disclose an 80% green tea extract, that that is sufficient to render obvious any amount of green tea extract. This is incorrect. There is nothing in the Yasuda et al. publication to disclose or suggest the selection of these particular amounts of catechols and caffeine to administer in a daily dose. Thus, Yasuda et al. does not disclose or suggest each and every element of the presently claimed invention.

Further, Yasuda et al. do not provide any motivation to select a composition comprising a green tea extract containing the particular amounts recited in a daily dose. In fact, Yasuda et al. further separate out the various catechins and simply incorporate them on chewing gum in order to depress the production of CH_3SH . There is no motivation provided by Yasuda et al. to select the particular amounts for oral administration of a daily dose as recited in the present claims. The selection of these amounts is not simply a matter of scaling up or down as the Examiner suggests. Rather, the claimed amounts are optimized for particular levels of catechols and caffeine to provide synergistic thermogenic and anti-lipase properties. There must be a particular motivation or disclosure of the particular amounts recited. As noted above, Yasuda et al. were concerned with determining the effect of various tea catechins on combating bad breath. Yasuda does not mention any proportions of catechins as being efficacious for the purposes of fighting halitosis. Nowhere in the Yasuda publication is there any mention of caffeine, which is a critical part of the presently claimed invention, or any indication that a particular proportion of caffeine and catechols would be synergistic in helping to maintain a desired weight or to treat obesity. Yasuda et al. does not even utilize the green tea extract itself, but rather continues to further isolate the various catechin components. Thus, one skilled in the art would not find motivation or guidance in the Yasuda et al. publication to arrive at the presently claimed invention.

The presently claimed invention is also nonobvious as evidenced by the commercial success discussed in the Declaration of Max Rombi submitted previously. As can be seen from Paragraph 12 of the Declaration and the accompanying Exhibit 1, the novel green tea

extract, AR-25, as described in the specification, is experiencing commercial success. From the period of August 28, 2002 to November 12, 2002, more than 17,360 kg of AR-25 totaling \$677,040 were sold. Moreover, estimates from the distributor marketing AR-25 total 40,000 kg for the first quarter of 2003. The impressive commercial success of AR-25, a green tea extract according to the presently claimed invention, demonstrates that the presently claimed invention is not obvious.

Thus, a *prima facie* case of obviousness based on Yasuda et al. has not been established for failure to disclose or suggest all of the claimed elements and to provide motivation to arrive at the presently claimed invention. Additionally, the presently claimed invention is supported by evidence of commercial success, which is a further indication of nonobviousness. Accordingly, withdrawal of this rejection is respectfully requested.

Conclusions

From the foregoing, further and favorable action in the form of a Notice of Allowance is respectfully requested and such action is earnestly solicited.

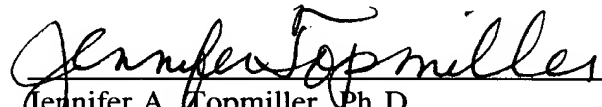
In the event that there are any questions concerning this amendment or the application in general, the Examiner is respectfully requested to telephone the undersigned so that prosecution of the application may be expedited.

Respectfully submitted,

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Attachment to Amendment dated July 7, 2003

Mark-up of Claims

1. (Five Times Amended) [An extract of green tea] A composition for the curative and prophylactic treatment of obesity, suitable for oral administration, comprising an extract of green tea having from 20% to 50% by mass of catechols expressed as epigallocatechol gallate (EGCG), and from 5% to 10% by mass of caffeine, said catechols and caffeine being present in said extract in a combined synergistic thermogenically effective amount, the ratio of the concentration of catechols to the concentration of caffeine in said extract being between 2 and 10.

3. (Four Times Amended) [An extract of green tea] A composition according to Claim 1, wherein said green tea extract has [comprising] from 20% to 30% by mass of catechols expressed as epigallocatechol gallate (EGCG).

5. (Four Times Amended) [An extract of green tea] The composition according to Claim 1, wherein said green tea extract has [comprising] from 250 mg to 500 mg of catechols, and from 50 mg to 200 mg of caffeine, per daily dose.

16. (Four Times Amended) [An extract of green tea] The composition according to Claim 5, wherein said green tea extract has [comprising] about 375 mg of catechols and about 150 mg of caffeine.

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25. (Amended) [An extract of green tea] A composition for the curative and prophylactic treatment of obesity, suitable for oral administration, comprising an extract of green tea having from 20% to 50% by mass of catechols expressed as epigallocatechol gallate (EGCG), and from 5% to 10% by mass of caffeine, said catechols and caffeine being present in said extract in a combined synergistic thermogenically effective amount, the ratio of the concentration of catechols to the concentration of caffeine in said extract being between 2 and 10 and wherein said green tea extract is obtained using an 80% ethanol extraction.

26. (Amended) [An extract of green tea] The composition according to Claim 1, wherein said green tea extract has [comprising] from 20% to 30% by mass of catechols expressed as epigallocatechol gallate (EGCG).

27. (Amended) [An extract of green tea] The composition according to Claim 1, wherein said green tea extract has [comprising] from 250 mg to 500 mg of catechols, and from 50 mg to 200 mg of caffeine, per daily dose.

28. (Amended) [An extract of green tea] The composition according to Claim 5, wherein said green tea extract has [comprising] about 375 mg of catechols and about 150 mg of caffeine.